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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,558	09/14/2001	Keiko Matsumoto	52740	7124

7590 07/28/2003

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,558

Applicant(s)

MATSUMOTO ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment B, received by the Office May 14, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,480,175. This reference discloses a pharmaceutical preparation in the form of coated tablets prepared by the direct compression of an active, wherein the composition can further comprise a lubricant, such as talc, magnesium stearate or stearic acid, an adjuvant, such as lactose or anhydrous calcium phosphate, and a disintegrant, such as starch.

The reference does not specifically teach the use of silicic anhydride as the lubricant, nor does it specifically discuss the angle of repose. Regarding the silicic anhydride, it is the position of the examiner that one of ordinary skill in the art would know that silicic anhydride is an acceptable equivalent for the likes of talc and magnesium stearate. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection.

Furthermore, regarding the angle of repose, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to

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establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Lastly, the reference does not specifically teach that the mixing be performed with a high speed mixer. It is the position of the examiner that this limitation does not render patentable distinction to the claims. The reference clearly teaches a process of making a composition comprising the same ingredients as claimed by Applicant, using the same process as claimed by Applicant. Employing a simple and well known piece of equipment, such as a mixer, to perform a task as simple as blending pharmaceutical components prior to direct compression, does not render patentability to the current invention.

One skilled in the art would have been motivated to create a tablet using direct compression, containing the ingredients claimed by Applicant, based on the teachings of the GB reference. The expected result would be a tablet formulation for pharmaceutical use. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 19-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10114655 (abstract). The reference discloses a pharmaceutical preparation, comprising a medicine, an additive and disintegrating agent. More specifically, the reference teaches that the

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excipient can be a salt of silicic acid, and the disintegrant can be crospovidone. Additionally, the IPER teaches that the reference teaches the use of lactose as an excipient, and specifically powdered anhydrous silicic acid as a lubricant (page 2, upper right column, line 16 – lower left column, line 6). The reference also teaches that the formulation is rapidly disintegratable.

The reference does not teach each and every one of the examples of excipients claimed by Applicant. However, the reference does teach at least one of each type of the claimed excipients. Furthermore, there is nothing specific in the abstract discussing the method of making the formulation. However, based on the broad language in Applicant's claim, it is the position of the examiner that the reference is suggestive of the basic method of blending powders together prior to direct compression to formulate a tablet. One of ordinary skill in the art would have been motivated to use this method to create a fast disintegrating tablets, using the specified materials. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has canceled the prior claims and replaced them with new claims 19-46. Applicant argues that the characteristic of their invention resides in the powder which is obtained by blending the active with the additives to achieve a particular angle of repose. However, Applicant has (1) not placed any criticality on the claimed angle of repose, or (2) provided scientific evidence that the compositions and methods discussed in the cited references do not produce a similar angle. The Office does not have the facilities for examining and comparing

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applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Additionally, Applicant argues that the invention is based upon the discovery that high flowability can be achieved without the use of any solvent, such as water. There are several problems with this argument, although the arguments are similar. First, this limitation is not found in the claim language and therefore has not been interpreted into the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the absence of a solvent such as water) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *See In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Second, Applicants have claimed very broad method claims, and have used comprising language, therefore not excluding the presence of additional method steps. Third, Applicant himself admits, at page 18 of the Response, that the success of this method without the use of any solvent, such as water, is critical to the invention. However, the claims, as recited, do not include this limitation. It is recommended that the critical features be inserted into the claim language.

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For the above reasons, the rejections are maintained and applied to the newly filed claims, as discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
July 24, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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